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Cunningham et al.

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(54) **STENT GRAFT WITH VALVE ARRANGEMENT**

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(52) **U.S. Cl.**
USPC **623/1.13**; 623/1.35

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See application file for complete search history.

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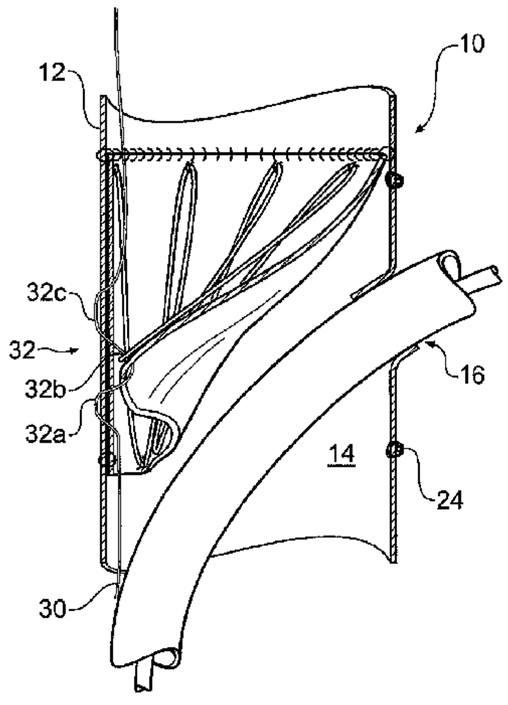
(57) **ABSTRACT**

A stent graft (**10**) has a tubular body with a side aperture (**16**) covered by a valve arrangement (**18**) and an arrangement to hold the valve open (**32**) with a release wire (**30**). Retraction of the release wire closes the valve. The stent graft can have a tubular body with a first bifurcation (**134**) with first and second legs (**130**, **132**) extending from the bifurcation. The side aperture and valve arrangement can be in one of the legs. One of the legs (**132**) has a further bifurcation (**142**) to define a side arm (**140**). The stent graft can be deployed into the vasculature of a patient with the tubular body being in an aorta of the patient, a first leg extending down an iliac artery, a second leg being directed towards a contralateral iliac artery and the side arm directed to an internal artery of the contralateral iliac artery.

20 Claims, 5 Drawing Sheets



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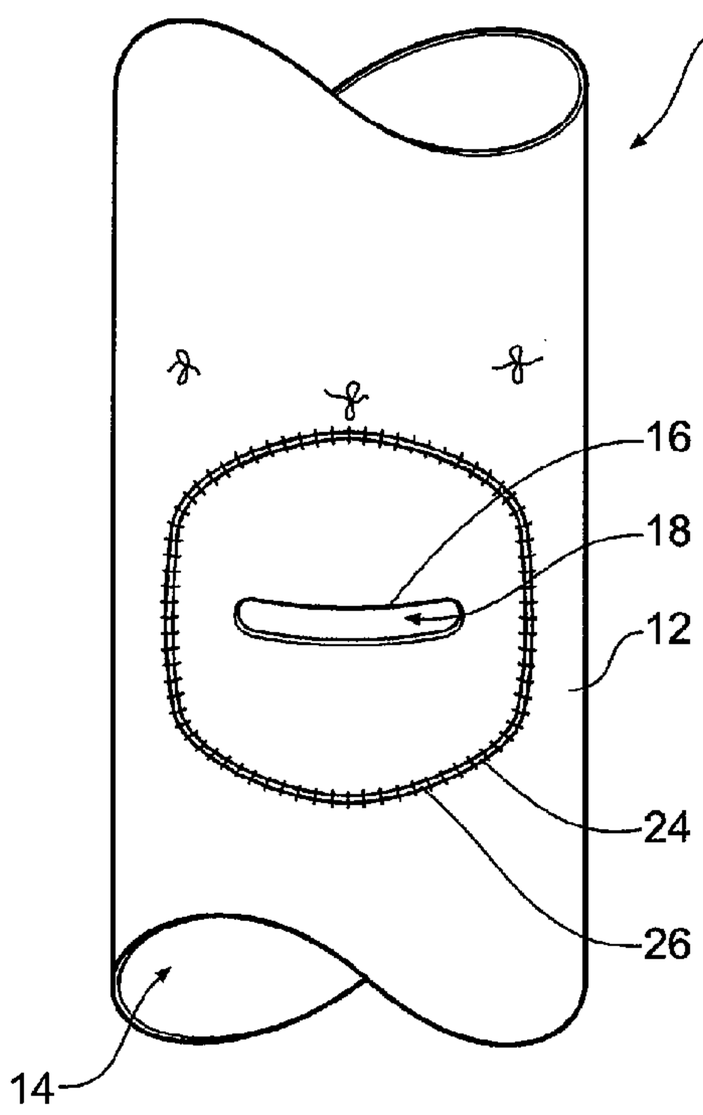

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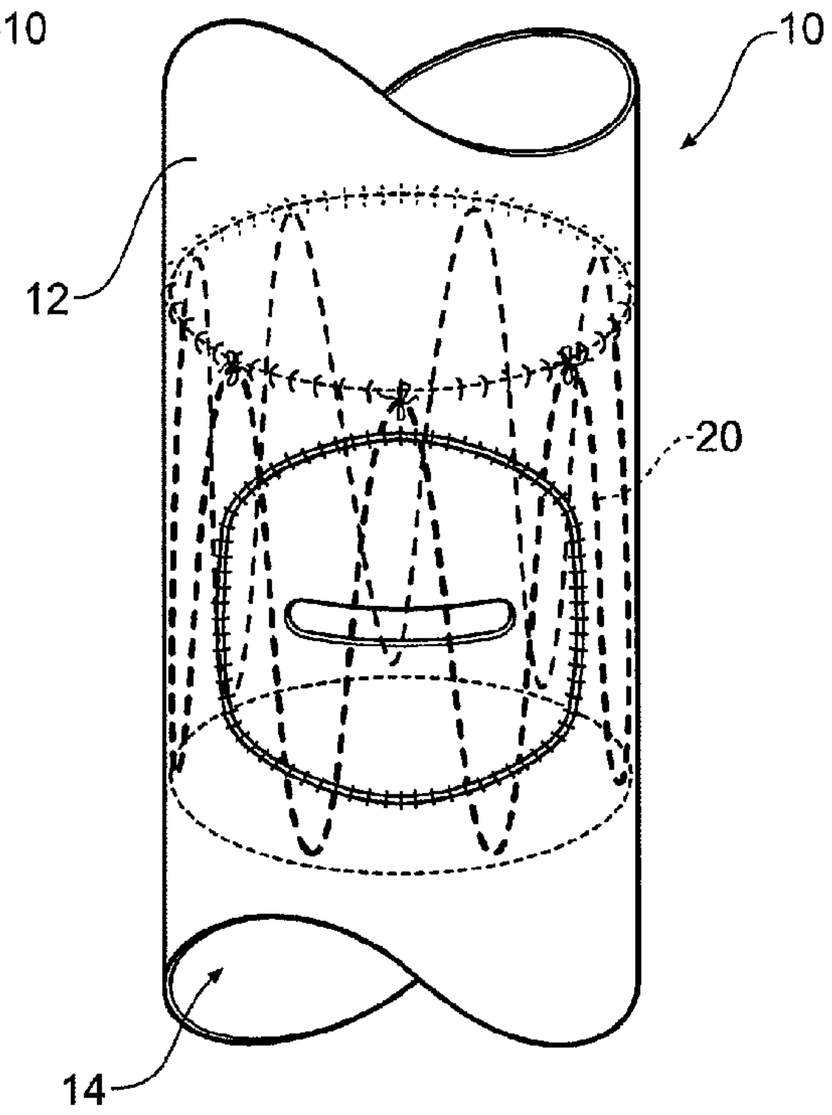

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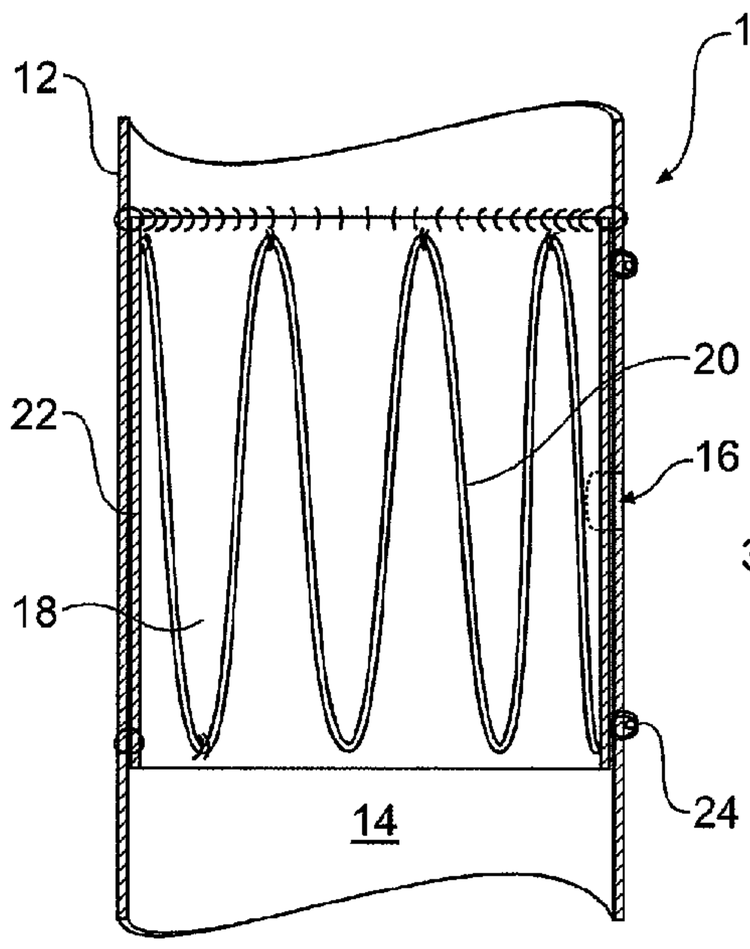

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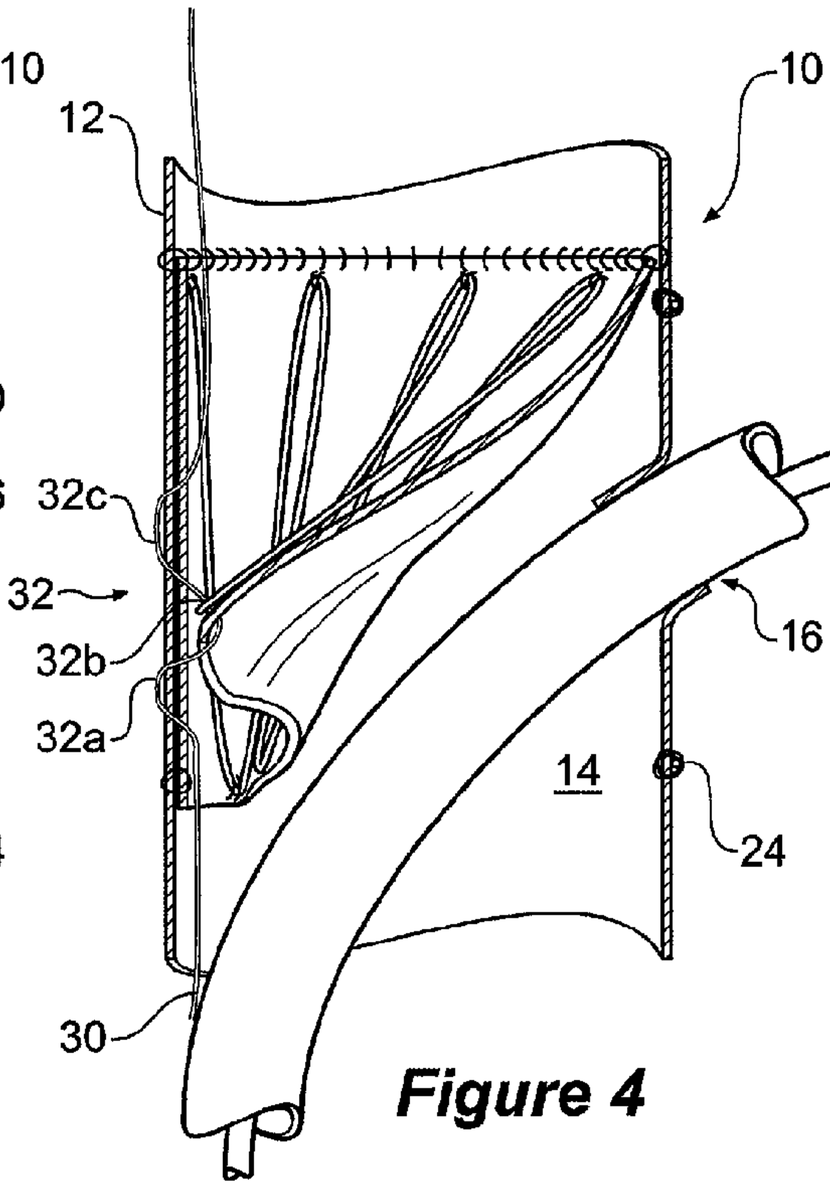

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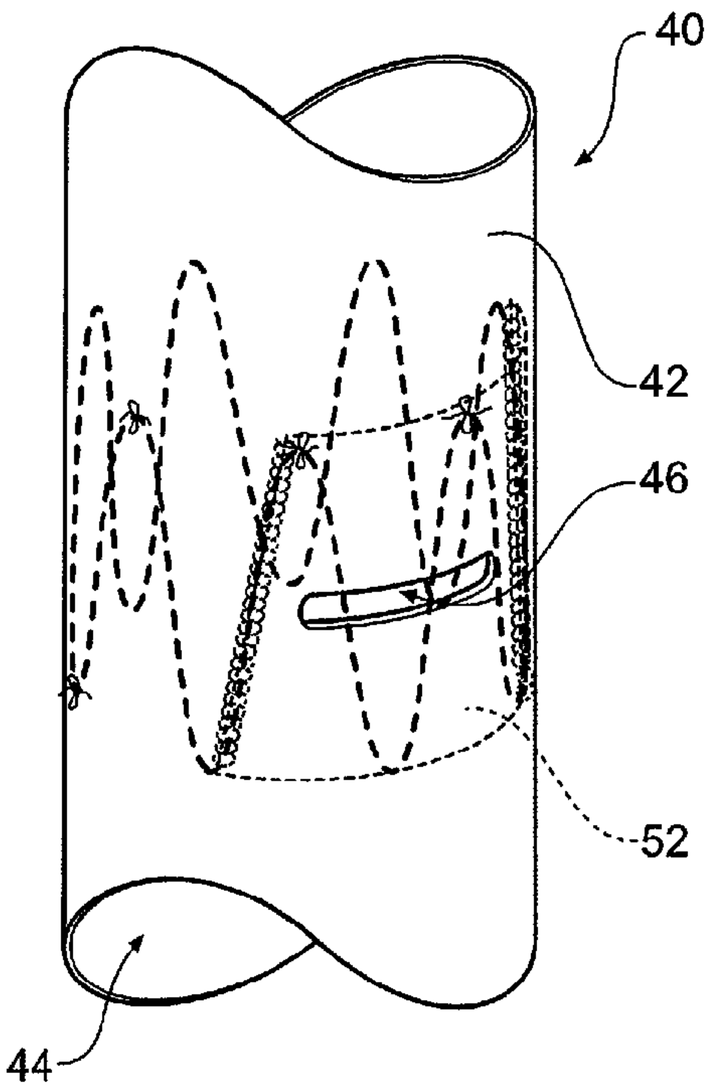

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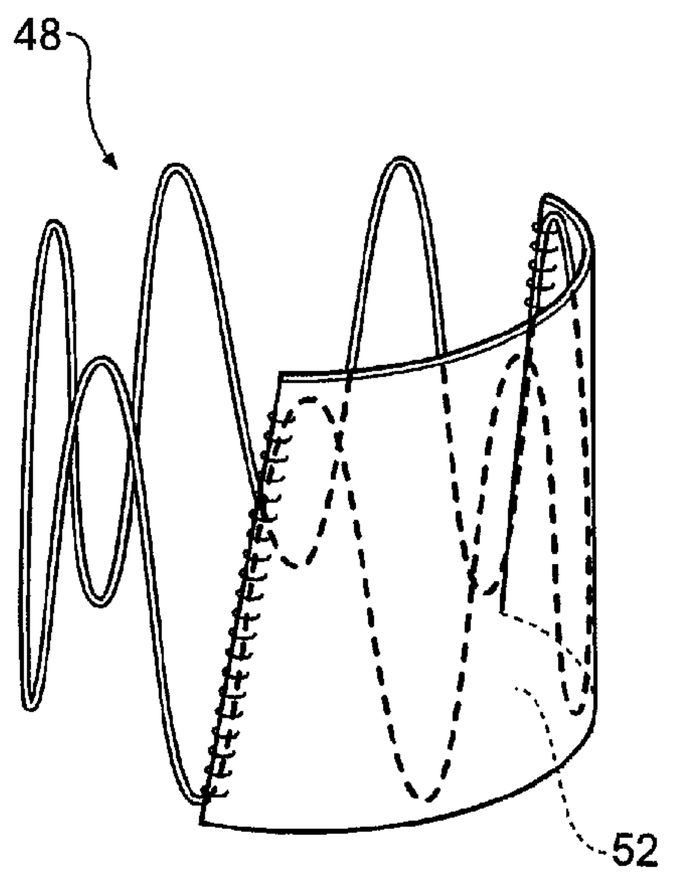

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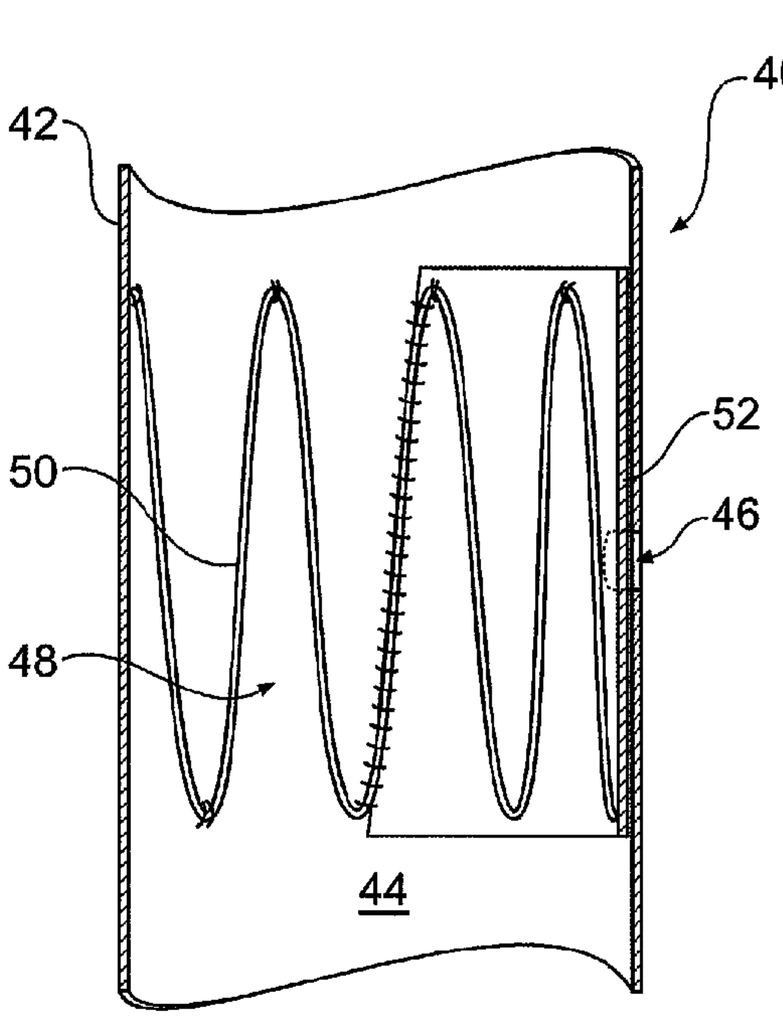

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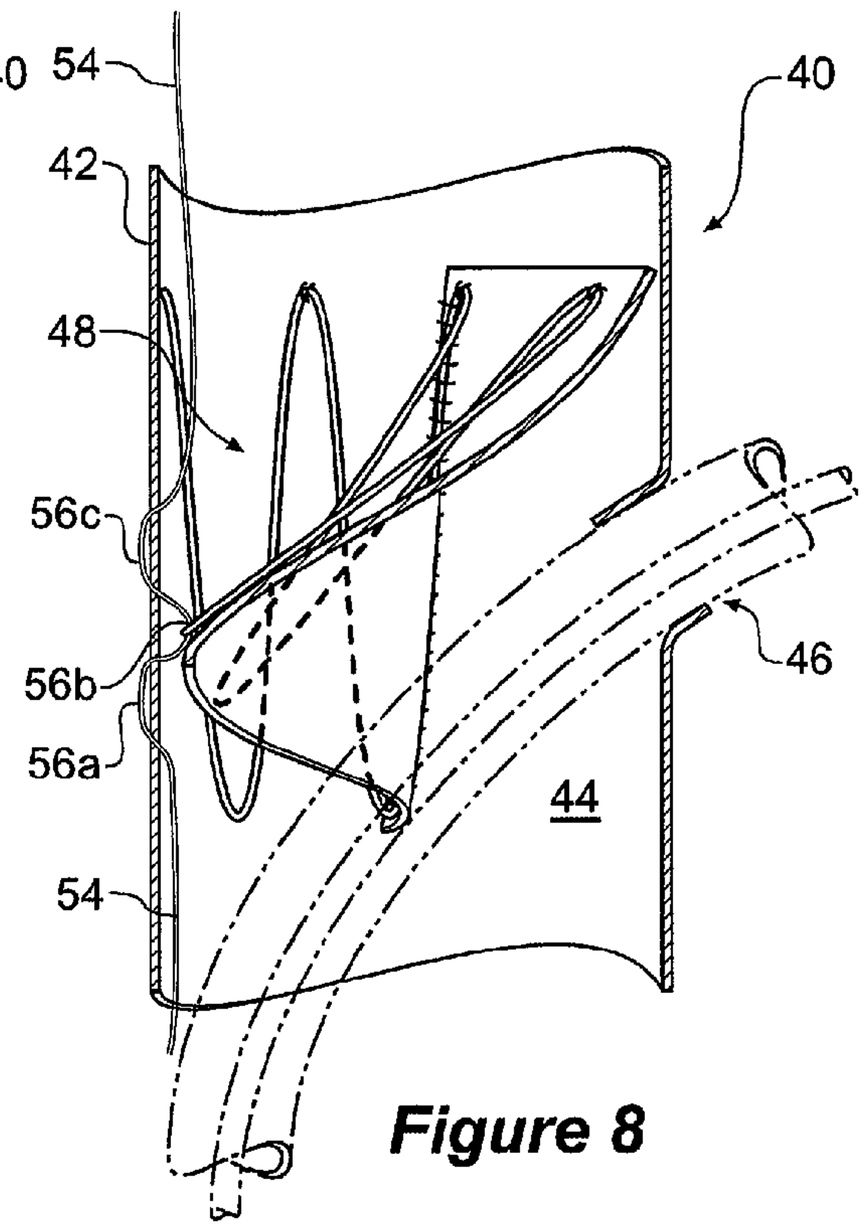

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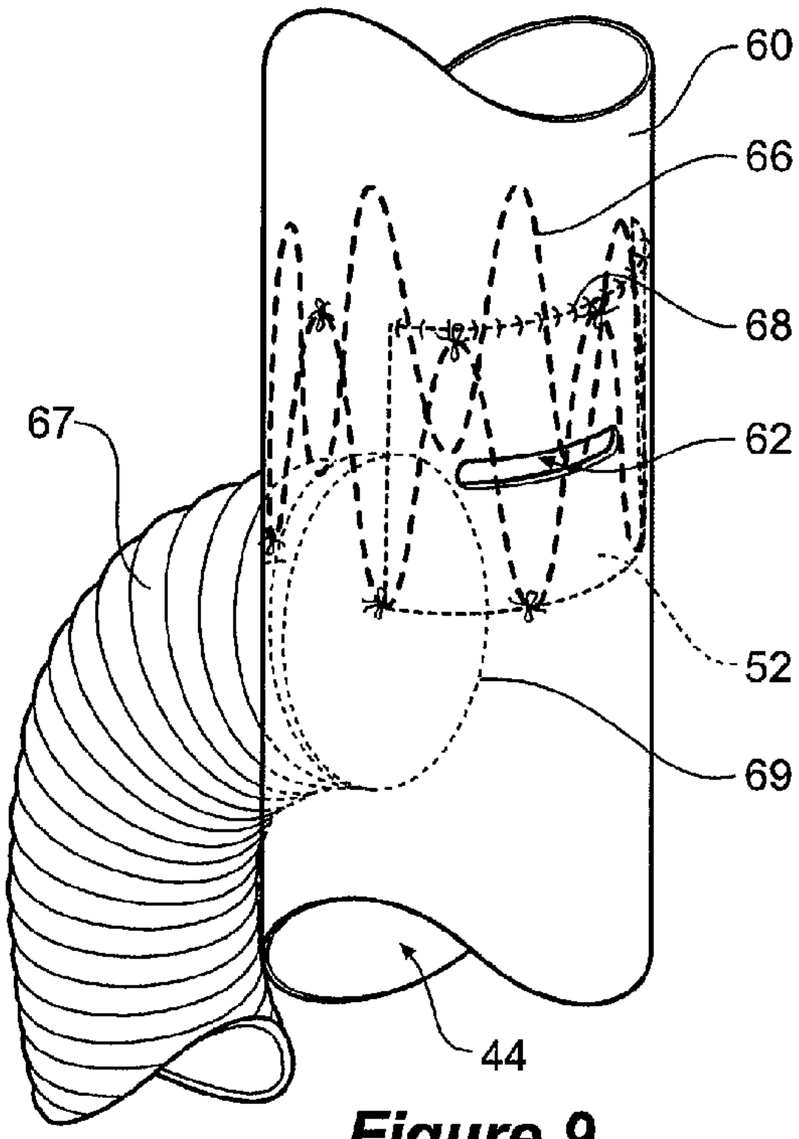

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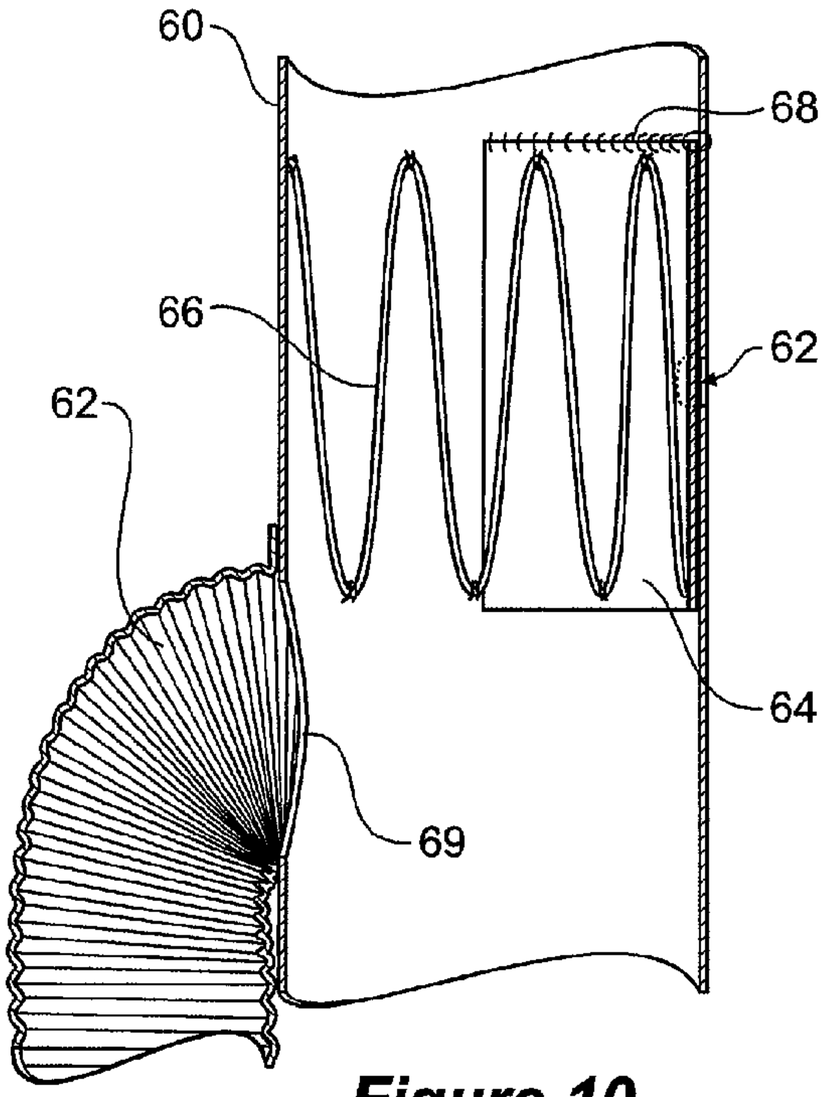

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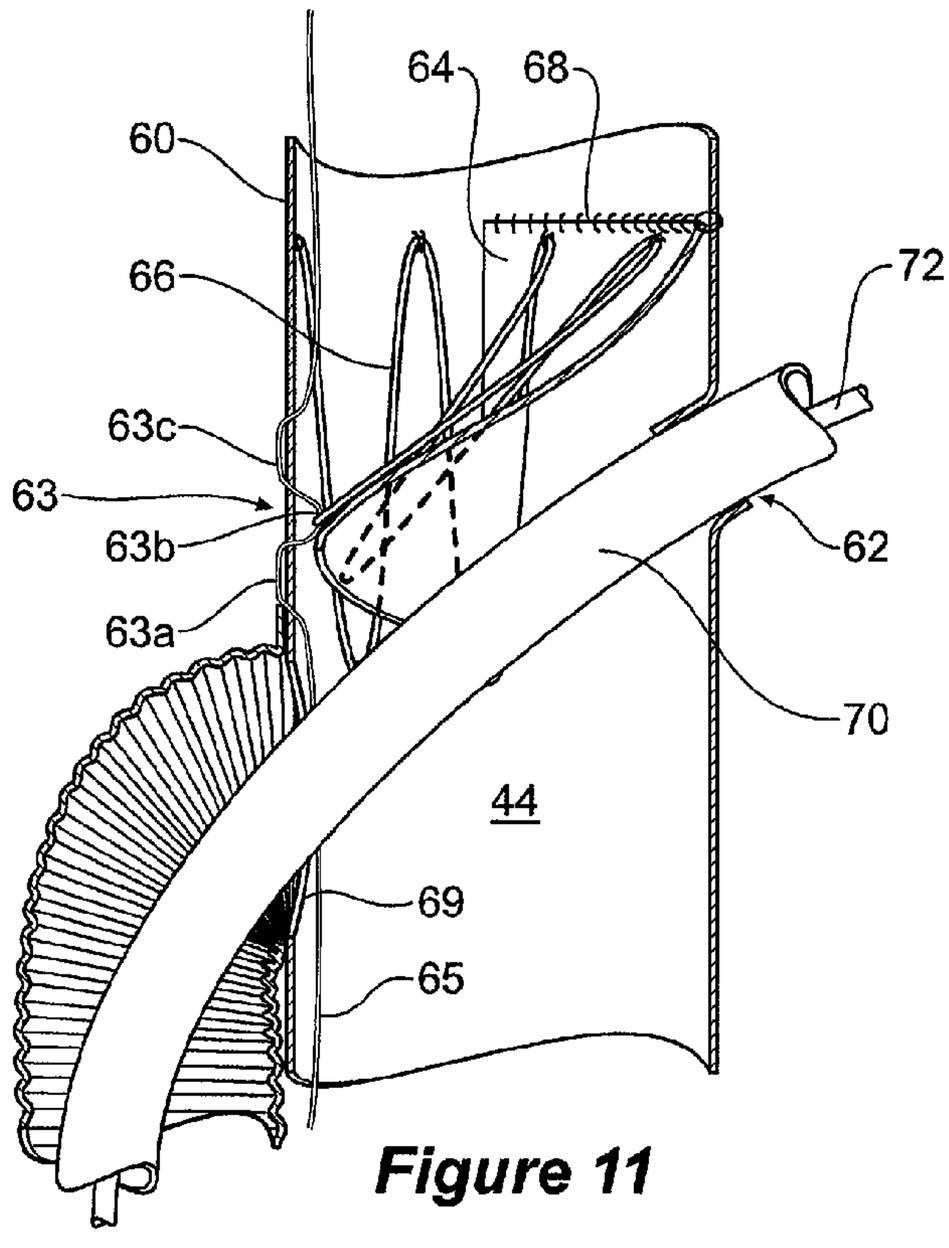

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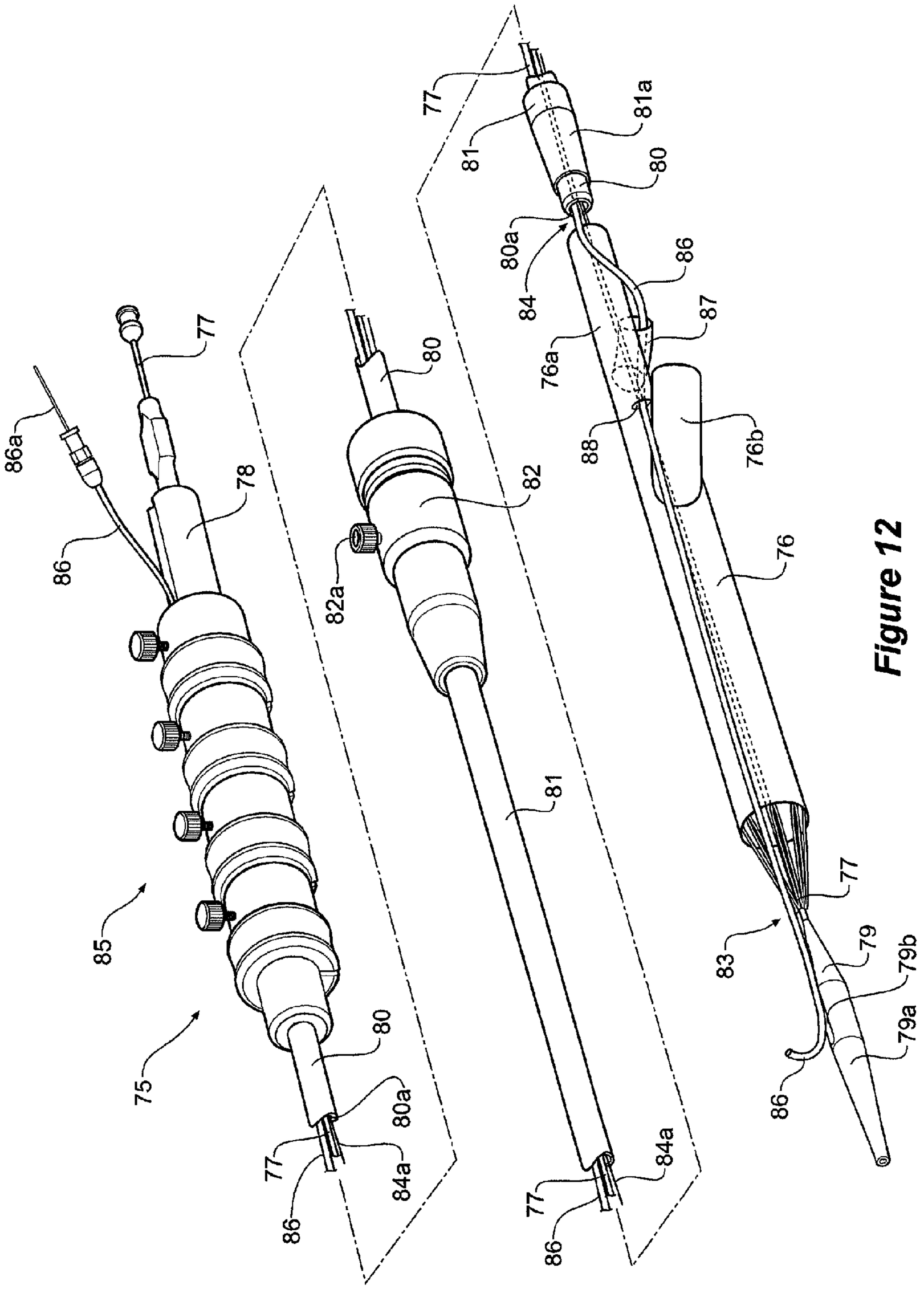
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Figure 12

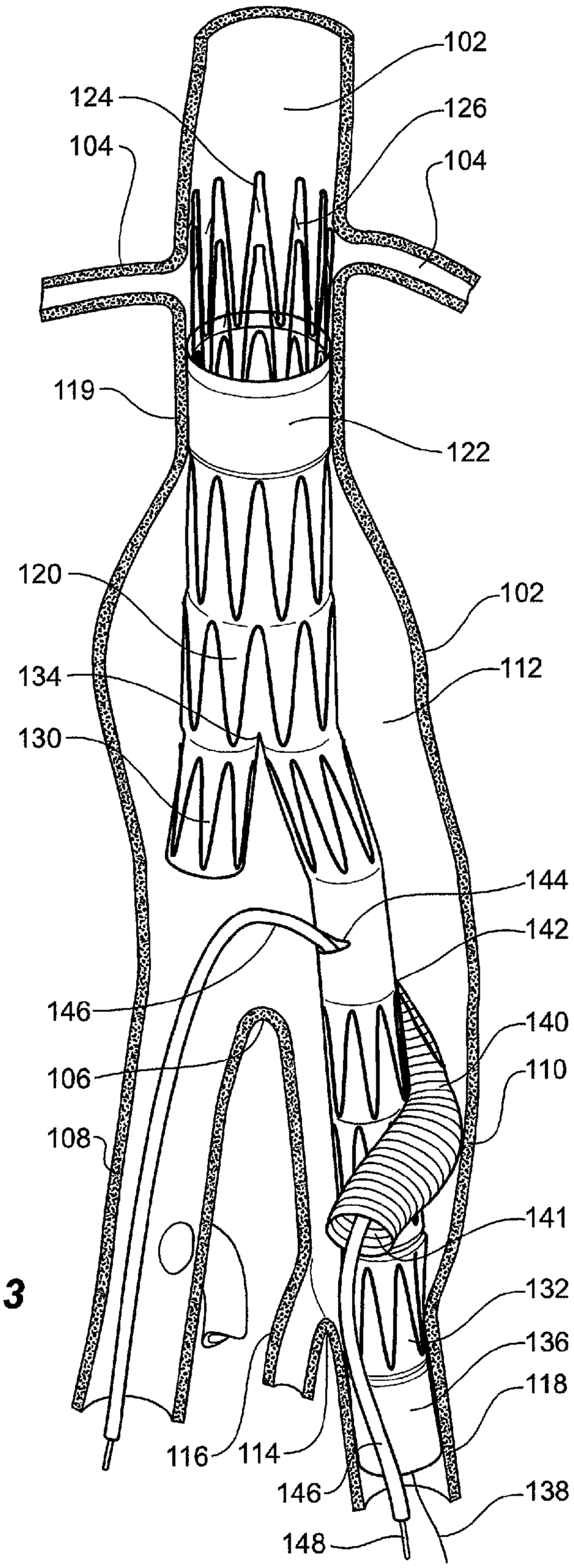
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Figure 13

STENT GRAFT WITH VALVE ARRANGEMENT

INCORPORATION BY REFERENCE

The following co-pending patent applications are referred to in the following description:

U.S. patent application Ser. No. 10/962,763 entitled "Introducer for Iliac Side Branch Device".

PCT Patent Publication No. WO 98/53761 entitled "A Prosthesis and a Method of Deploying a Prosthesis"

U.S. patent application Ser. No. 11/600,655 entitled "Stent Graft Introducer" (U.S. Publication 2007/0123910)

U.S. patent application Ser. No. 11/788,285 entitled "Twin Bifurcated Stent Graft" (U.S. Publication 2007/0250154)

The entire content of each of these applications is hereby incorporated by reference.

TECHNICAL FIELD

This invention relates to a medical device and more particularly a device which can be deployed by endovascular means into the vasculature of a patient.

BACKGROUND OF THE INVENTION

Endovascular devices such a stent graft are use to repair defects in the vasculature if a patient. In some procedures it is necessary to provide a valve arrangement in the wall of a stent graft to allow temporary access during introduction of the endovascular device.

An object of this invention is to provide a valve arrangement in such situations or at least provide a physician with a useful alternative. There have been proposed bifurcated endovascular devices which can be deployed into the vasculature, particularly in the region of the aortic bifurcation, so that an aneurysm in the aorta can be bridged by placement of the endovascular device. In use a proximal portion of such a device seals into a non-aneurysed portion of the aorta adjacent to the renal arteries, a first leg extends down one iliac artery to a non-aneurysed portion of the iliac artery and another short leg extends towards the contra-lateral iliac artery. A leg extension may be placed to extend from the short leg into a non-aneurysed portion of the contra-lateral iliac artery.

There can be problems, however, if the aneurysm of the aorta extends down into one or other of the iliac arteries. Each of the common iliac arteries branches into the internal and external iliac arteries and it is necessary in such a situation that a blood flow path can be directed through an endovascular stent graft into each of these arteries.

The further object of this invention is to provide a single endovascularly deployed medical device which can solve this problem or at least provide a physician with a useful alternative.

Throughout this specification the term distal with respect to a portion of the aorta, a deployment device or a prosthesis means the end of the aorta, deployment device or prosthesis further away in the direction of blood flow away from the heart and the term proximal means the portion of the aorta, deployment device or end of the prosthesis nearer to the heart. When applied to other vessels similar terms such as caudal and cranial should be understood.

SUMMARY OF THE INVENTION

In one form therefore the invention is said to reside in a stent graft delivery device in combination with a stent graft,

the stent graft comprising a tubular body of a biocompatible graft material defining a lumen therethrough, the tubular body comprising a side aperture and a valve arrangement associated with the tubular body to prevent fluid flow through the aperture from inside of the tubular body to outside of the tubular body,

the stent graft delivery device comprising a distal end of the delivery device to remain outside a patient in use and a proximal end of the delivery device to be introduced into a patient in use,

an arrangement to retain the stent graft on the introducer device adjacent to the proximal end of the delivery device,

the distal end of the delivery device comprising a release wire mechanism and a release wire extending from the release wire mechanism towards and into the main lumen of the stent graft and engaging the valve arrangement to hold the valve arrangement away from the side aperture,

whereby activation of the release wire mechanism retracts the release wire and releases the valve arrangement such that the valve arrangement closes off the side aperture.

Preferably the stent graft delivery device comprising a guide wire catheter, the guide wire catheter extending from the distal end of the delivery device to the proximal end of the delivery device,

a pusher catheter over the guide wire catheter and extending from the distal end of the delivery device to a proximal pusher catheter end, the pusher catheter comprising a pusher lumen and the guide wire catheter extending through the pusher lumen,

a nose cone dilator on the guide wire catheter at the proximal introducer end and the stent graft being retained on the introducer device distally of the nose cone dilator and proximally of the proximal pusher end,

the release wire mechanism extending through the pusher lumen and into the main lumen of the stent graft to engage the valve arrangement.

Preferably the side aperture comprises a transverse slit in the tubular body.

Preferably the valve arrangement comprises a sleeve of a biocompatible graft material within the tubular body and a self expanding stent within the sleeve, the sleeve being fastened at its proximal end to the tubular body proximally of the aperture and the self expanding stent being fastened to the sleeve, whereby the self expanding stent forces the sleeve against the inner surface of the first leg around the aperture to prevent fluid flow through the aperture from inside of the leg to outside of the leg. The sleeve of a biocompatible graft material can comprise a cylindrical form. Alternatively the sleeve of a biocompatible graft material can comprise a semi-cylindrical form.

Preferably the valve arrangement comprises a self expanding stent to which a part cylindrical portion of biocompatible graft material is stitched along spaced apart struts of the self expanding stent, the self expanding stent and sleeve being fastened at their proximal ends to the tubular body proximally of the aperture.

Preferably the engagement of the release wire with the valve arrangement comprises the release wire being stitched into the graft material of the tubular body and then into the valve arrangement and then into the graft material of the tubular body again.

Preferably the engagement of the release wire with the graft material of the tubular body comprises stitching the release wire into the graft material at a position on the tubular body substantially opposite to the side aperture.

Preferably the valve arrangement comprises a self expanding stent and a sleeve of biocompatible graft material and the

engagement of the release wire with the valve arrangement comprises stitching the release wire around a strut or apex of the self expanding stent.

In an alternative form the invention comprises a stent graft delivery device in combination with a stent graft,

the stent graft comprising a tubular body of a biocompatible graft material defining a main lumen therethrough, a bifurcation in the tubular body at one end thereof and a first leg and a second leg extending from the bifurcation, the first leg being a long leg and the second leg being a short leg, the first and second legs having respective first and second lumens therethrough and the first and second lumens being in fluid communication with the main lumen, the first leg comprising a side arm with a side arm lumen therethrough and the side arm lumen being in fluid communication with the first leg lumen, the first leg comprising a side aperture and a valve arrangement to prevent fluid flow through the aperture from inside of the leg to outside of the leg, the side aperture comprising a transverse slit,

the stent graft delivery device comprising a distal end intended to remain outside a patient in use and a proximal end to be introduced into a patient in use, the stent graft delivery device comprising a guide wire catheter, the guide wire catheter extending from a distal introducer end to a proximal introducer end, a pusher catheter over the guide wire catheter and extending from the distal introducer end to a proximal pusher end, the pusher catheter comprising a pusher lumen and the guide wire catheter extending through the pusher lumen, a nose cone dilator on the guide wire catheter at the proximal introducer end and an arrangement to retain the stent graft on the introducer device distally of the nose cone dilator and proximally of the proximal pusher end,

the guide wire catheter extending through the first leg lumen and the main lumen of the main tubular body,

the distal end of the delivery device comprising a release wire mechanism and a release wire extending from the release wire mechanism through the pusher lumen and into the first lumen of the stent graft and engaging the valve arrangement to hold the valve arrangement away from the side aperture,

whereby activation of the release wire mechanism retracts the release wire and releases the valve arrangement such that the valve arrangement closes off the side aperture.

Preferably the valve arrangement comprises a sleeve of a biocompatible graft material within the tubular body and a self expanding stent within the sleeve, the sleeve being fastened at its proximal end to the tubular body proximally of the aperture and the self expanding stent being fastened to the sleeve, whereby the self expanding stent forces the sleeve against the inner surface of the first leg around the aperture to prevent fluid flow through the aperture from inside of the leg to outside of the leg. The sleeve of a biocompatible graft material can comprise a cylindrical form. Alternatively the sleeve of a biocompatible graft material can comprise a semi-cylindrical form.

Preferably the valve arrangement comprises a valve assembly comprising a self expanding stent to which a part cylindrical portion of biocompatible graft material is stitched along spaced apart struts of the self expanding stent, the self expanding stent and sleeve being fastened at their proximal ends to the tubular body proximally of the aperture.

Preferably the engagement of the release wire with the valve arrangement comprises the release wire being stitched into the graft material of the first leg and then into the valve arrangement and then into the graft material of the first leg again.

Preferably the engagement of the release wire with the graft material of the first leg comprises stitching the release wire into the graft material at a position on the first leg substantially opposite to the side aperture.

Preferably the valve arrangement comprises a self expanding stent and a sleeve of biocompatible graft material and the engagement of the release wire with the valve arrangement comprises stitching the release wire around a strut of the self expanding stent.

Preferably the stent graft delivery device further includes an indwelling catheter extending from the distal introducer end through the pusher lumen in the pusher catheter to the stent graft,

the indwelling catheter exiting from the pusher lumen at a distal end of the branched stent graft, the indwelling catheter then extending along and outside of the first long leg of the stent graft and then entering the distal open end of the side arm, the indwelling catheter then extending through the side arm lumen to the first leg lumen and then extending out of the side aperture and then extending outside and along the tubular body of the stent graft to the nose cone dilator, the indwelling catheter having an indwelling guide wire extending therethrough, whereby the indwelling guide wire can be extended beyond the nose cone dilator in use,

whereby the stent graft can be deployed into the vasculature of a patient with the tubular body being in an aorta of the patient, the first leg extending down a common iliac artery, the second leg being directed towards a contra-lateral common iliac artery and the side arm on the first leg directed to an internal iliac artery of the ipsilateral common iliac artery.

In an alternative form the invention comprises a stent graft delivery device in combination with a stent graft,

the stent graft comprising a tubular body of a biocompatible graft material defining a main lumen therethrough, a bifurcation in the tubular body at one end thereof and a first leg and a second leg extending from the bifurcation, the first leg being a long leg and the second leg being a short leg, the first and second legs having respective first and second lumens therethrough and the first and second lumens being in fluid communication with the main lumen, the first long leg comprising a side arm with a side arm lumen therethrough and the side arm lumen being in fluid communication with the first leg lumen, the first leg comprising a side aperture and a valve arrangement to prevent fluid flow through the aperture from inside of the leg to outside of the leg, the side aperture comprising a transverse slit,

the stent graft delivery device comprising a distal end intended to remain outside a patient in use and a proximal end to be introduced into a patient in use, the stent graft delivery device comprising a guide wire catheter, the guide wire catheter extending from a distal introducer end to a proximal introducer end, a pusher catheter over the guide wire catheter and extending from the distal introducer end to a proximal pusher end, the pusher catheter comprising a pusher lumen and the guide wire catheter extending through the pusher lumen, a nose cone dilator on the guide wire catheter at the proximal introducer end and an arrangement to retain the stent graft on the introducer device distally of the nose cone dilator and proximally of the proximal pusher end,

the guide wire catheter extending through the first leg lumen and the main lumen of the main tubular body,

an indwelling catheter extending from the distal introducer end through the pusher lumen in the pusher catheter to the stent graft, the indwelling catheter exiting from the pusher lumen at a distal end of the branched stent graft, the indwelling catheter then extending along and outside of the first long leg of the stent graft and then entering the distal open end of the side arm, the indwelling catheter then extending through the side arm lumen to the first leg lumen and then extending

out of the side aperture and then extending outside and along the tubular body of the stent graft to the nose cone dilator, the indwelling catheter having an indwelling guide wire extending therethrough, whereby the indwelling guide wire can be extended beyond the nose cone dilator in use,

the distal end of the delivery device comprising a release wire mechanism and a release wire extending from the release wire mechanism through the pusher lumen and into the first lumen of the stent graft and engaging the valve arrangement to hold the valve arrangement away from the side aperture,

the engagement of the release wire with the valve arrangement comprises the release wire being stitched into the graft material of the first leg and then into the valve arrangement and then into the graft material of the first leg again.

whereby activation of the release wire mechanism retracts the release wire and releases the valve arrangement such that the valve arrangement closes off the side aperture.

The biocompatible graft material can include polytetrafluoroethylene, Dacron, polyamide or any other suitable biocompatible graft material. While Dacron, expanded polytetrafluoroethylene (ePTFE), or other synthetic biocompatible materials can be used for the tubular graft material for the stent graft, a naturally occurring biomaterial, such as collagen, is highly desirable, particularly a specially derived collagen material known as an extracellular matrix (ECM), such as small intestinal submucosa (SIS). Besides SIS, examples of ECM's include pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa, and dura mater. SIS is particularly useful, and can be made in the fashion described in Badylak et al., U.S. Pat. No. 4,902,508; Intestinal Collagen Layer described in U.S. Pat. No. 5,733,337 to Carr and in 17 Nature Biotechnology 1083 (November 1999); Cook et al., WIPO Publication WO 98/22158, dated 28 May 1998, which is the published application of PCT/US97/14855, the teachings of which are incorporated herein by reference. Irrespective of the origin of the material (synthetic versus naturally occurring), the material can be made thicker by making multilaminate constructs, for example SIS constructs as described in U.S. Pat. Nos. 5,968,096; 5,955,110; 5,885,619; and 5,711,969. In addition to xenogenic biomaterials, such as SIS, autologous tissue can be harvested as well, for use in forming the tubular graft material. Additionally Elastin or Elastin-Like Polypetides (ELPs) and the like offer potential as a material to fabricate the tubular graft material to form a device with exceptional biocompatibility.

SIS is available from Cook Biotech, West Lafayette, Ind., USA. U.S. patent application Ser. No. 11/788,285 entitled "Twin Bifurcated Stent Graft" (US Publication 2007/0250154) describes the use of a bifurcated graft which includes a further bifurcation on one of its legs to enable cathertisation of an internal iliac artery and the teachings therein are incorporated herein in their entirety. The aperture and valve arrangement in the tubular body or side arm allows an indwelling catheter to be provided through the sidearm in the iliac artery at the time of deployment to assist with deployment of leg extension into the internal iliac artery.

U.S. patent application Ser. No. 10/962,763 entitled "Introducer for Iliac Side Branch Device" discloses an arrangement for using an indwelling catheter to access an internal iliac artery and the teaching of this specification is incorporated herewith in its entirety.

In this case the indwelling catheter can be extended and its guide wire snared from the contra-lateral artery and the leg extension placed into the ipsilateral internal iliac artery before the leg extension is placed into the contralateral iliac artery.

This then generally describes the invention but to assist with understanding reference will now be made to the accompanying drawings which show further embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWING

In the drawings;

FIG. **1** shows a tubular body of one embodiment of a stent graft incorporating a side aperture and valve arrangement according to the present invention;

FIG. **2** shows the embodiment of FIG. **1** with the internal components shown dotted;

FIG. **3** shows a cross section of the embodiment shown in FIG. **1** rotated axially by 45°;

FIG. **4** shows a cross section of the embodiment shown in FIG. **1** rotated axially by 90° with the valve arrangement retracted from the side aperture and a catheter extending through the side aperture;

FIG. **5** shows a tubular body of an alternative embodiment of a stent graft incorporating a side aperture and valve arrangement according to the present invention;

FIG. **6** shows a detail of the valve arrangement of FIG. **5** showing the self expanding stent with a valve member mounted onto it;

FIG. **7** shows a cross section of the embodiment shown in FIG. **5** rotated axially by 45°;

FIG. **8** shows a cross section of the embodiment shown in FIG. **5** rotated axially by 45° with the valve arrangement retracted from the side aperture and a catheter extending through the side aperture;

FIG. **9** shows a leg and side arm extending from the leg of a bifurcated stent graft of an alternative embodiment of a stent graft incorporating a side aperture and valve arrangement according to the present invention;

FIG. **10** shows a cross section of the embodiment shown in FIG. **9** rotated axially by 45°;

FIG. **11** shows a cross section of the embodiment shown in FIG. **9** rotated axially by 45° with the valve arrangement retracted from the side aperture and a catheter extending through the side aperture;

FIG. **12** shows a schematic view of a stent graft loaded onto a delivery device according to the present invention; and

FIG. **13** shows an embodiment of stent graft and indwelling catheter according to the invention deployed into the vasculature before placement of an iliac side branch.

DETAILED DESCRIPTION

Looking more closely at the drawings and in particular FIGS. **1** and **4** show a schematic view of part of a tubular body of one embodiment of a stent graft incorporating a side aperture and valve arrangement according to the present invention.

FIG. **1** shows a tubular body of a stent graft incorporating a side aperture and valve arrangement according to the present invention, FIG. **2** shows a detail of the valve arrangement of FIG. **1**, FIG. **3** shows a cross section of the embodiment shown in FIG. **1** and FIG. **4** shows a cross section of the embodiment shown in FIG. **1** with the valve arrangement retracted from the side aperture and a catheter extending through the side aperture.

A stent graft **10** in this embodiment comprises a tubular body **12** of a biocompatible graft material defining a lumen **14** therethrough The tubular body has a side aperture **16** and a valve arrangement **18** associated with the tubular body to prevent fluid flow through the aperture from inside of the

tubular to outside of the tubular body. The aperture in this embodiment is a transverse slot which is considerably longer than it is wide. The region of the tubular body around the aperture **16** is reinforced with a substantially circular ring of reinforcement wire **24** spaced away from the aperture and stitched to the tubular body by stitches **26**. The reinforcement wire may for instance be formed from nitinol or stainless steel.

The side aperture **16** is preferably of such a length that it can allow a catheter for deploying a side branch leg extension through it as is discussed below. Such a catheter may be a 8 to 10 French catheter. Where the tubular body of the stent graft is formed from a material such as Dacron the edges of the aperture may be heat sealed to prevent unravelling of the weave of the graft material.

The valve arrangement **18** has a self expanding stent **20** and a cylindrical biocompatible graft material sleeve **22**. The sleeve **22** engages onto the tubular body **12** around the aperture **16** and acts a valve preventing flow through the valve and the stent **20** holds the sleeve against the tubular body **12** around the aperture **16** as can be particularly seen in the cross sectional view of FIG. **3**, for instance. The self expanding stent may for instance be formed from nitinol or stainless steel.

As shown in FIG. **4** the valve arrangement can be held retracted from the aperture **16** to allow unrestricted access for a catheter through the side aperture **16** during deployment of a branch stent graft which will be discussed in more detail below. The valve arrangement is held retracted by a release wire arrangement. A release wire **30** extends through the lumen **14** of tubular body **12** and is stitched into the tubular body at a position **32** substantially opposite to the side aperture **16**. The release wire **30** is first stitched onto the tubular body at **32***a* and then through the valve arrangement at **32***b* and then through the tubular body again at **32***c*. By this arrangement the valve is held retracted from the side aperture and movement of a catheter through the aperture is not hindered. The release wire is either engaged with the graft material of the valve sleeve **22**, with one or more struts or apex of the stent **20** associated with the valve arrangement or with both of these.

FIG. **5** shows a tubular body of an alternative embodiment of a stent graft incorporating a side aperture and valve arrangement according to the present invention, FIG. **6** shows a detail of the valve arrangement of FIG. **5** showing the self expanding stent with a valve member mounted onto it, FIG. **7** shows a cross section of the embodiment shown in FIG. **5** and FIG. **8** shows a cross section of the embodiment shown in FIG. **5** with the valve arrangement retracted from the side aperture and a catheter extending through the side aperture.

A stent graft **40** in this embodiment comprises a tubular body **42** of a biocompatible graft material defining a lumen **44** therethrough The tubular body has a side aperture **46** and a valve arrangement **48** associated with the tubular body to prevent fluid flow through the aperture from inside of the tubular body to outside of the tubular body. The aperture in this embodiment is a transverse slot which is considerably longer than it is wide.

The valve arrangement has a self expanding stent **50** and a part cylindrical biocompatible graft material sleeve **52** stitched onto struts of the stent. The sleeve **52** engages onto the tubular body **42** around the aperture **46** and acts as a valve preventing flow through the valve and the stent **50** holds the sleeve against the tubular body **42** around the aperture **46** as can be particularly seen in FIG. **7**, for instance.

As shown in FIG. **8** the valve arrangement **48** can be held retracted from the aperture **46** to allow unrestricted access for a catheter through the side aperture during deployment of a branch stent graft which will be discussed in more detail below. The valve arrangement is held retracted by a release wire arrangement. A release wire **54** extends through the lumen **44** of tubular body **42** and is stitched into the tubular body at a position **56** substantially opposite to the side aperture **46**. The release wire **54** is first stitched onto the tubular body at **56***a* and then through the valve arrangement at **56***b* and then through the tubular body again at **56***c*. By this arrangement the valve is held retracted from the side aperture and movement of a catheter through the aperture is not hindered.

The release wire is either engaged with the graft material of the valve sleeve **52**, with one or more struts or apex of the stent **50** associated with the valve arrangement or with any combination of these.

FIGS. **9**, **10** and **11** show a further embodiment of valve arrangement suitable for the present invention.

In this embodiment part of the longer leg **60** of a bifurcated stent graft, for instance as shown in FIG. **12** below, is shown. The longer leg **60** has an elongate aperture, slit or fenestration **62**. Inside the longer leg **60** is a semi-circular portion **64** of biocompatible graft material **52** and a resilient self-expanding zigzag stent **66** which engages with the semi-circular biocompatible graft material **52** and engages it against the inside wall of the longer leg **60** and in particular over the slit or fenestration **62**. By this arrangement the slit or fenestration **62** is held in a closed configuration. The semi-circular piece of material **64** is stitched by stitching **68** at its proximal end to the inner wall of the longer leg **60**.

Substantially opposite to the elongate slit **62** in the tubular longer leg **60** a side arm **67** extends from a fenestration **69** in the tubular longer leg **60**.

FIG. **11** shows the embodiment as shown in FIGS. **9** and **10** except that an indwelling catheter **70** and guide wire **72** through the indwelling catheter extend through the side arm **67** and through the fenestration **69**. The semi-circular piece of material **64** is held off the elongate slit against the restoring force of the resilient self expanding stent **66** by a release wire mechanism.

The release wire mechanism comprises a release wire **65** extending from a release mechanism on a delivery device upon (not shown) which the stent graft, of which the long leg **60** is part, is mounted. The release wire **65** extends through the lumen of the long leg **60** and is stitched into the long leg at a position **63** substantially opposite to the side aperture **62**. The release wire **65** is first stitched onto the tubular body at **63***a* and then through the valve arrangement at **63***b* and then through the tubular body again at **63***c*. By this arrangement the valve member is held retracted from the side aperture and movement of a catheter through the aperture is not hindered.

The release wire is either engaged with the graft material of the valve sleeve **52**, with one or more struts of the stent **66** associated with the valve arrangement or with both of these.

FIG. **12** shows a schematic view of a stent graft **76** loaded onto a delivery device **75** according to the present invention. The delivery device **75** has a guide wire catheter **77** which extends from a distal handle **78** to the proximal tapered nose cone dilator **79** longitudinally through a passageway or lumen **80***a* of a pusher catheter **80** which is connected to the handle **78** at its distal end. An introducer sheath **81** fits coaxially around the pusher catheter **80** and extends from a tapered proximal end **81** a which optionally includes a radiopaque marker to a connector valve and hub **82** attached to the distal end of the sheath. The introducer sheath **81** extends proximally to the nose cone dilator **79** and covers the stent graft **76** during introduction of the deployment device into a patient

and is withdrawn distally to expose the stent graft **76** during deployment when the deployment device is in a selected position within the vasculature of a patient. The sheath **81** is shown in the retracted position in FIG. **12**.

The stent graft or implantable device **76** is carried on the guide wire catheter **77** proximally of the pusher catheter **80** and distally of the nose cone dilator **79**. The stent graft **76** comprises a tubular body of a biocompatible material and a plurality of self expanding stents (not shown for clarity) Towards its distal end the stent graft is bifurcated into a longer leg **76***a* and a shorter leg **76***b*. The stent graft includes on the longer leg **76***a* a side arm which extends part helically around the long leg **76***a*. A transverse elongate slit aperture **88** is provided in the long leg **76***a* and a valve arrangement (see FIGS. **1** to **11**) is provided to close off the slit aperture.

Connector valve and hub **82** includes a silicone disk assembly (not shown) for preventing the backflow of fluids therethrough. The disk assembly includes a slit for the insertion of the nose cone dilator **79** and delivery catheter **80**. Connector and hub **82** also includes side arm **82***a* to which a tube may be connected for introducing and aspirating fluids therethrough. Nose cone dilator **79** includes a tapered proximal end **79***a* for accessing and dilating a vascular access site over a well-known and commercially available wire guide (not shown).

The stent graft has a proximal retention arrangement **83** immediately distal of the nose cone dilator **79** on the guide wire catheter **77** and a distal retention arrangement **84** on the long leg **76***a* at the proximal end of the pusher catheter **80**. Release wires extend from each of the proximal and distal retention arrangements to release mechanisms **85** on the handle **78**. The release wire **84***a* for the distal retention **84** also extends to the valve arrangement and holds the valve member off the slit aperture as discussed in relation to and as shown in FIG. **4**, for instance.

An indwelling catheter **86** enters the handle **78** and extends through the lumen **80***a* of the pusher catheter **80** and exits the pusher catheter at its proximal end. The indwelling catheter then extends along and on the outside of the long leg **76***a* and enters the distal end of the side arm **87** into the lumen of the long leg and then exits the slit aperture **88** and extends along and on the outside of the stent graft **76** to the nose cone dilator **79**. The nose cone dilator has a elongate groove **79***b* in its outer surface and the indwelling catheter extends along the groove. The indwelling catheter **86** has an indwelling guide wire **86***a*. The indwelling catheter can have a pre-curved proximal end **86***b*. The pre-curved proximal end of the indwelling catheter having its proximal end in the elongate groove, wherein in a partially retracted position of the introducer sheath the pre-curved proximal end of the indwelling catheter is exposed and in a curved configuration and not covered by the sleeve and in an advanced position of the introducer sheath the pre-curved proximal end of the indwelling auxiliary catheter is in a straightened configuration, extends along the groove in the nose cone and is covered by the introducer sheath. The indwelling guide wire can be extended to be snared from a contra-lateral iliac artery as discussed below.

U.S. patent application Ser. No. 11/600,655 entitled "Stent Graft Introducer" (US Publication 2007/0123910) discusses the use of indwelling catheters with curved proximal ends and the teachings therein are incorporated herein in their entirety.

FIG. **13** shows a schematic view of a stent graft with a valve arrangement according to the invention deployed into the vasculature before placement of an iliac side branch. In practice, the stent graft would not be as shown in use because a delivery device would be present but this has been omitted for clarity.

The vasculature comprises an aorta **102** in the region between the renal arteries **104** and the aortic bifurcation **106**. Common iliac arteries **108** and **110** extend down from the aortic bifurcation **106**. The aorta **102** has an aneurysm **112** which extends down into the common iliac artery **110** as far as the bifurcation **114** between the internal iliac artery **116** and the external iliac artery **118**.

To traverse the aneurysm **112** a twin bifurcated aortic stent graft **120** according to one embodiment of the present invention has been deployed into the aorta **102**. In this drawing the introduction device which is used to deploy the stent graft into the vasculature has been omitted to assist clarity. In our earlier patent application, PCT Patent Publication No. WO 98/53761 entitled "A prosthesis and a method deploying a prosthesis" there is disclosed an introducer for a stent graft which is suitable for use with the present invention. The proximal end **122** of the bifurcated stent graft **120** is engaged into non-aneurysed portion **119** of the aorta **102** just distal of the renal arteries **104**. In this embodiment stent graft **120** has a proximally extending supra-renal exposed stent **124** with barbs **126** engaging the wall of the aorta proximal of the renal arteries to provide a secure position to prevent migration of the stent graft. The stent graft **120** has a short leg **130** and a long leg **132** extending from the graft bifurcation **134**. The longer leg **132** has a sealing surface **136** at its distal end which engages into a non-aneurysed portion of the external iliac artery **118**.

The longer leg **132** has a side arm **140** which in this embodiment is in the form of a corrugated tube extending in a part helical manner from its connection at a fenestration **142** into the longer leg **132**. The side arm **140** extends in a distal direction and helically partly around the longer leg **132** and has a distal end **141** remote from its connection with the longer leg **132** which opens adjacent to the internal iliac artery **116**.

A transverse slit **144** is placed into the longer leg **132** in the region of the connection of the side arm **140** into the longer leg **132**. The transverse slit **144** has a valve arrangement within it to close it off as discussed above with reference to FIGS. **1** to **11**. A release wire **138** extends up through the long leg **132** and engages the valve member within the long leg on the region of the transverse slit **144** and holds the valve member away from the transverse slit as discussed above on relation to FIG. **4**, for instance. The release wire **138** extends at its distal end to a release mechanism on a delivery device (see FIG. **12**). The release wire **138** may also act as a releasable release mechanism for the distal end of the long leg where it is temporarily retained onto the delivery device.

During deployment of the stent graft into the vasculature of a patient an indwelling catheter **146** extends through the side arm **140** and out through the valved transverse slit **144** as discussed in relation to FIG. **12**. The indwelling catheter includes an auxiliary guide wire **148**. As illustrated the indwelling catheter is depicted extending down the contra-lateral artery. At this stage the indwelling catheter and guide wire is as described below a through-and-through auxiliary guide wire within the indwelling catheter from one iliac artery to the other.

A process for use of the stent graft and delivery device of the present invention is discussed below.

The various stages of deployment of a stent graft incorporating a valve arrangement according to one embodiment of the present invention are as follows.

A delivery device has a nose cone dilator at its proximal end and a stent graft assembly according to one embodiment of the present invention is mounted onto the deployment device. This embodiment of stent graft has a helical side arm on the longer leg of the stent graft. An indwelling catheter

extends from the deployment device through the helical side arm exiting at valved aperture and extending to a groove in the nose cone dilator outside of the stent graft. The indwelling catheter has a flexible curved proximal end. An embodiment of such a stent graft mounted onto a delivery device is shown in FIG. **12**.

Details of various embodiments of the tubular side arm and valve arrangement are shown in FIGS. **1** to **11**. The tubular side arm **140** extends around the longer leg **132** from a fenestration **142** and the indwelling catheter **146** extends into the tubular side arm and out through the valved aperture **144**. The valved aperture **144** has a flap valve on its inside to ensure that the aperture is closed when the indwelling catheter is removed. The flap valve is substantially the same as the as the construction shown in FIGS. **3** to **6**.

The deployment device is deployed over a guide wire so that its nose cone extends up into the aneurysm to be spanned and the distal end of the nose cone is substantially adjacent to an aortic bifurcation. The sheath of the deployment device is withdrawn slightly to release the curved tip of the indwelling catheter and the indwelling guide wire from the indwelling catheter is extended. Because of the curved end of the indwelling catheter the indwelling guide wire extends down the contra-lateral iliac artery. A snare catheter is deployed into the contra-lateral common iliac artery and a snare of the snare catheter is extended to grasp the guide wire. The guide wire is extracted via the snare catheter so that it becomes a through-and-through guide wire from one iliac artery to the other. It is important at this stage to ensure there is slack maintained in the guide wire at the aortic bifurcation to prevent damage to the aortic bifurcation.

The use of an indwelling catheter with a curved tip to facilitate snaring from a contra-lateral iliac artery is taught in U.S. patent application Ser. No. 11/600,655 entitled 'Stent Graft Introducer ' and the teaching therein is incorporated herein in its entirety.

The deployment device is then advanced so that the nose cone dilator is proximal of the renal arteries. This draws the indwelling guide wire also up into the aorta. The sheath of the deployment device is then withdrawn to release the shorter leg of the stent graft. The indwelling catheter is then withdrawn down into the contra-lateral iliac artery and the sheath is withdrawn so that it is distal of the distal end of the side arm while still retaining the distal end of the longer leg.

A dilator and sheath is then advanced over the guide wire in the contra-lateral iliac artery and the indwelling catheter and extension arm deployment device are tracked over the guide wire so that the nose cone of the dilator enters the valved slit aperture and tracks over the guide wire into the side arm until it exits the distal end of the side arm. The dilator is then withdrawn leaving the sheath in place. At this stage the indwelling guide wire is still in a through-and-through position. A second guide wire is introduced through the sheath and extended from the sheath to enter into the internal iliac artery. A side arm deployment device is then deployed over the second guide wire into the internal iliac artery so that balloon expandable covered stent, for instance, extends into the internal iliac artery from the side arm. The indwelling guide wire is then removed and the position of the distal end of the longer leg is set into the external iliac artery and the balloon expandable covered stent is expanded. The sheath is then withdrawn and the valve release mechanism released so that the valve closes. A leg extension can then placed into the short leg of the graft. The proximal end of the stent graft is also released from the deployment device such that a portion of the graft seals into a non-aneurysed portion of the aorta distal of the renal arteries while an uncovered suprarenal stent extends over the renal arteries to provide secure fixation.

U.S. patent application Ser. No. 11/788,285 entitled "Twin Bifurcated Stent Graft" (US Publication 2007/0250154) discloses methods of deployment of bifurcated stent grafts which have a further bifurcation on one of the bifurcated legs and deployment of a leg extension into such stent grafts and the teachings therein a incorporated herein in their entirety.

Throughout this specification various indications have been given as to the scope of invention but invention not limited to any one of these but may reside in two or more of these combined together. The examples are given for illustration only and not for limitations.

What is claimed is:

1. A stent graft delivery device in combination
with a stent graft,
the stent graft comprising a tubular body of a biocompatible graft material defining a lumen therethrough, the tubular body comprising a side aperture and a valve arrangement associated with the tubular body to prevent fluid flow through the aperture from inside of the tubular body to outside of the tubular body,
the stent graft delivery device comprising a distal end of the delivery device to remain outside a patient in use and a proximal end of the delivery device to be introduced into a patient in use,
an arrangement to retain the stent graft on the stent craft delivery device adjacent to the proximal end of the delivery device,
the distal end of the delivery device comprising a release wire mechanism and a release wire extending from the release wire mechanism towards and into the main lumen of the stent graft and engaging the valve arrangement to hold the valve arrangement away from the side aperture,
whereby activation of the release wire mechanism retracts the release wire and releases the valve arrangement such that the valve arrangement closes off the side aperture.

2. A stent graft delivery device in combination with a stent graft as in claim **1** wherein the stent graft delivery device comprising a guide wire catheter, the guide wire catheter extending from the distal end of the delivery device to the proximal end of the delivery device,
a pusher catheter over the guide wire catheter and extending from the distal end of the delivery device to a proximal pusher catheter end, the pusher catheter comprising a pusher lumen and the guide wire catheter extending through the pusher lumen,
a nose cone dilator on the guide wire catheter at the proximal introducer end and the stent graft being retained on the introducer device distally of the nose cone dilator and proximally of the proximal pusher end,
the release wire mechanism extending through the pusher lumen and into the main lumen of the stent graft to engage the valve arrangement.

3. A stent graft delivery device in combination with a stent graft as in claim **1** wherein the side aperture comprises a transverse slit in the tubular body.

4. A stent graft delivery device in combination with a stent graft as in claim **1** wherein the valve arrangement comprises a sleeve of a biocompatible graft material within the tubular body and a self expanding stent within the sleeve, the sleeve being fastened at its proximal end to the tubular body proximally of the aperture and the self expanding stent being fastened to the sleeve, whereby the self expanding stent forces the sleeve against an inner surface of the tubular body around

the aperture to prevent fluid flow through the aperture from inside of the tubular body to outside of the tubular body.

5. A stent graft delivery device in combination with a stent graft as in claim **4** wherein the sleeve of a biocompatible graft material comprises a cylindrical form.

6. A stent graft delivery device in combination with a stent graft as in claim **4** wherein the sleeve of a biocompatible graft material comprises a semi-cylindrical form.

7. A stent graft delivery device in combination with a stent graft as in claim **1** wherein the valve arrangement comprises a valve assembly comprising a self expanding stent to which a part cylindrical portion of biocompatible graft material is stitched along spaced apart struts of the self expanding stent, the self expanding stent and sleeve being fastened at their proximal ends to the tubular body proximally of the aperture.

8. A stent graft delivery device in combination with a stent graft as in claim **1** wherein the engagement of the release wire with the valve arrangement comprises the release wire being stitched into the graft material of the tubular body and then into the valve arrangement and then into the graft material of the tubular body again.

9. A stent graft delivery device in combination with a stent graft as in claim **8** wherein the engagement of the release wire with the graft material of the tubular body comprises stitching the release wire into the graft material at a position on the tubular body substantially opposite to the side aperture.

10. A stent graft delivery device in combination with a stent graft as in claim **8** wherein the valve arrangement comprises a self expanding stent and a sleeve of biocompatible graft material and the engagement of the release wire with the valve arrangement comprises stitching the release wire around a strut or apex of the self expanding stent.

11. A stent graft delivery device in combination with a stent graft,

the stent graft comprising a tubular body of a biocompatible graft material defining a main lumen therethrough, a bifurcation in the tubular body at one end thereof and a first leg and a second leg extending from the bifurcation, the first leg being a long leg and the second leg being a short leg, the first and second legs having respective first and second lumens therethrough and the first and second lumens being in fluid communication with the main lumen, the first leg comprising a side arm with a side arm lumen therethrough and the side arm lumen being in fluid communication with the first leg lumen, the first leg comprising a side aperture and a valve arrangement to prevent fluid flow through the aperture from inside of the leg to outside of the leg, the side aperture comprising a transverse slit,

the stent graft delivery device comprising a distal end intended to remain outside a patient in use and a proximal end to be introduced into a patient in use, the stent graft delivery device comprising a guide wire catheter, the guide wire catheter extending from a distal introducer end to a proximal introducer end, a pusher catheter over the guide wire catheter and extending from the distal introducer end to a proximal pusher end, the pusher catheter comprising a pusher lumen and the guide wire catheter extending through the pusher lumen, a nose cone dilator on the guide wire catheter at the proximal introducer end and an arrangement to retain the stent graft on the introducer device distally of the nose cone dilator and proximally of the proximal pusher end,

the guide wire catheter extending through the first leg lumen and the main lumen of the main tubular body,

the distal end of the delivery device comprising a release wire mechanism and a release wire extending from the release wire mechanism through the pusher lumen and into the first lumen of the stent graft and engaging the valve arrangement to hold the valve arrangement away from the side aperture,

whereby activation of the release wire mechanism retracts the release wire and releases the valve arrangement such that the valve arrangement closes off the side aperture.

12. A stent graft delivery device in combination with a stent graft as in claim **11** wherein the valve arrangement comprises a sleeve of a biocompatible graft material within the first leg and a self expanding stent within the sleeve, the sleeve being fastened at its proximal end to the first leg proximal of the aperture and the self expanding stent being fastened to the sleeve, whereby the self expanding stent forces the sleeve against the inner surface of the first leg around the aperture to prevent fluid flow through the aperture from inside of the leg to outside of the leg.

13. A stent graft delivery device in combination with a stent graft as in claim **12** wherein the sleeve of a biocompatible graft material comprises a cylindrical form.

14. A stent graft delivery device in combination with a stent graft as in claim **12** wherein the sleeve of a biocompatible graft material comprises a semi-cylindrical form.

15. A stent graft delivery device in combination with a stent graft as in claim **11** wherein the valve arrangement comprises a valve assembly comprising a self expanding stent to which a part cylindrical portion of biocompatible graft material is stitched along spaced apart struts of the self expanding stent, the self expanding stent and sleeve being fastened at their proximal ends to the tubular body proximally of the aperture.

16. A stent graft delivery device in combination with a stent graft as in claim **11** wherein the engagement of the release wire with the valve arrangement comprises the release wire being stitched into the graft material of the first leg and then into the valve arrangement and then into the graft material of the first leg again.

17. A stent graft delivery device in combination with a stent graft as in claim **16** wherein the engagement of the release wire with the graft material of the first leg comprises stitching the release wire into the graft material at a position on the first leg substantially opposite to the side aperture.

18. A stent graft delivery device in combination with a stent graft as in claim **16** wherein the valve arrangement comprises a self expanding stent and a sleeve of biocompatible graft material and the engagement of the release wire with the valve arrangement comprises stitching the release wire around a strut or apex of the self expanding stent.

19. A stent graft delivery device in combination with a stent graft as in claim **11** further including an indwelling catheter extending from the distal introducer end through the pusher lumen in the pusher catheter to the stent graft,

the indwelling catheter exiting from the pusher lumen at a distal end of the branched stent graft, the indwelling catheter then extending along and outside of the first long leg of the stent graft and then entering the distal open end of the side arm, the indwelling catheter then extending through the side arm lumen to the first leg lumen and then extending out of the side aperture and then extending outside and along the tubular body of the stent graft to the nose cone dilator, the indwelling catheter having an indwelling guide wire extending therethrough, whereby the indwelling guide wire can be extended beyond the nose cone dilator in use.

20. A stent graft delivery device in combination with a stent graft,

the stent graft comprising a tubular body of a biocompatible graft material defining a main lumen therethrough, a bifurcation in the tubular body at one end thereof and a first leg and a second leg extending from the bifurcation, the first leg being a long leg and the second leg being a short leg, the first and second legs having respective first and second lumens therethrough and the first and second lumens being in fluid communication with the main lumen, the first long leg comprising a side arm with a side arm lumen therethrough and the side arm lumen being in fluid communication with the first leg lumen, the first leg comprising a side aperture and a valve arrangement to prevent fluid flow through the aperture from inside of the leg to outside of the leg, the side aperture comprising a transverse slit, the valve arrangement comprising a self expanding stent and a sleeve of biocompatible graft material;

the stent graft delivery device comprising a distal end intended to remain outside a patient in use and a proximal end to be introduced into a patient in use, the stent graft delivery device comprising a guide wire catheter, the guide wire catheter extending from a distal introducer end to a proximal introducer end, a pusher catheter over the guide wire catheter and extending from the distal introducer end to a proximal pusher end, the pusher catheter comprising a pusher lumen and the guide wire catheter extending through the pusher lumen, a nose cone dilator on the guide wire catheter at the proximal introducer end and an arrangement to retain the stent graft on the introducer device distally of the nose cone dilator and proximally of the proximal pusher end,

the guide wire catheter extending through the first leg lumen and the main lumen of the main tubular body,

an indwelling catheter extending from the distal introducer end through the pusher lumen in the pusher catheter to the stent graft,

the indwelling catheter exiting from the pusher lumen at a distal end of the branched stent graft, the indwelling catheter then extending along and outside of the first long leg of the stent graft and then entering the distal open end of the side arm, the indwelling catheter then extending through the side arm lumen to the first leg lumen and then extending out of the side aperture and then extending outside and along the tubular body of the stent graft to the nose cone dilator, the indwelling catheter having an indwelling guide wire extending therethrough, whereby the indwelling guide wire can be extended beyond the nose cone dilator in use,

the distal end of the delivery device comprising a release wire mechanism and a release wire extending from the release wire mechanism through the pusher lumen and into the first lumen of the stent graft and engaging the valve arrangement to hold the valve arrangement away from the side aperture,

the engagement of the release wire with the valve arrangement comprises the release wire being stitched into the graft material of the first leg and then into the valve arrangement or around a strut or apex of the self expanding stent and then into the graft material of the first leg again

whereby activation of the release wire mechanism retracts the release wire and releases the valve arrangement such that the valve arrangement closes off the side aperture.

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